in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(c)).

(d) Devices containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(e) Devices containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, that are not already subject to paragraph (d) of this section, shall bear the following statement in bold print on the device labeling:

''This Product Contains Dry Natural Rubber.''

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(f) Devices that have packaging containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.

(g) Devices that have packaging containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''The Packaging of This Product Contains Dry Natural Rubber.''

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.–

(h) Devices that contain natural rubber that contacts humans, as described in paragraph (b) of this section, shall not contain the term ''hypoallergenic'' on their labeling.

(i) Any affected person may request an exemption or variance from the requirements of this section by submitting a citizen petition in accordance with §10.30 of this chapter.

(j) Any device subject to this section that is not labeled in accordance with paragraphs (d) through (h) of this section and that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a), (c), and (f) of the act (21 U.S.C. 321(n) and 352(a), (c), and (f)).

NOTE TO §801.437: Paragraphs (f) and (g) are stayed until June 27, 1999, as those regulations relate to device packaging that uses ''cold seal'' adhesives.

[62 FR 51029, Sept. 30, 1997, as amended at 63 FR 46175, Aug. 31, 1998]

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

SOURCE: 60 FR 63597, Dec. 11, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 803.1 Scope.

(a) This part establishes requirements for medical device reporting. Under this part, device user facilities, importers, and manufacturers, as defined in § 803.3, must report deaths and serious injuries to which a device has or may have caused or contributed, must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports. Medical device distributors, as defined in § 803.3, are also required to maintain records of incidents (files). Furthermore, manufacturers and importers are also required to report certain device malfunctions. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(b) This part supplements and does not supersede other provisions of this subchapter, including the provisions of part 820 of this chapter.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[60 FR 63597, Dec. 11, 1995, as amended at 62 FR 13306, Mar. 20, 1997; 65 FR 4118, Jan. 26, 2000]

§ 803.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Ambulatory surgical facility (ASF)* means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

(c) *Become aware* means that an employee of the entity required to report has acquired information reasonably suggesting a reportable adverse event has occurred.

(1) Device user facilities are considered to have ''become aware'' when medical personnel, as defined in paragraph (s) of this section, who are employed by or otherwise formally affiliated with the facility, acquire such information about a reportable event.

(2) Manufacturers are considered to have become aware of an event when:

(i) Any employee becomes aware of a reportable event that is required to be reported within 30 days or that is required to be reported within 5 days under a written request from FDA under § 803.53(b); and

(ii) Any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becomes aware that a reportable MDR event or events, from

any information, including any trend analysis, necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

(3) Importers are considered to have become aware of an event when any employee becomes aware of a reportable event that is required to be reported by an importer within 30 days.

(d) *Caused or contributed* means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

(1) Failure;

(2) Malfunction;

(3) Improper or inadequate design;

(4) Manufacture;

(5) Labeling; or

(6) User error.

(e)(1) *Device family* means a group of one or more devices manufactured by or for the same manufacturer and having the same:

(i) Basic design and performance characteristics related to device safety and effectiveness,

(ii) Intended use and function, and

(iii) Device classification and product code.

(2) Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family. Factors such as brand name and common name of the device and whether the devices were introduced into commercial distribution under the same 510(k) or premarket approval application (PMA), may be considered in grouping products into device families.

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in paragraphs (b), (l), (t), (u), and (v), respectively, of this section, which is not a ''physician's office,'' as defined in paragraph (x) of this section. School nurse offices and employee health units are not device user facilities.

(g) *Distributor* means, for the purposes of this part, any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under paragraph (o) of this section.

(h) [Reserved]

(i) *Expected life* of a device (required on the manufacturer's baseline report) means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified ''end of life'' (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through maintenance, repair, upgrades, etc., for an estimated period of time.

(j) *FDA* means the Food and Drug Administration.

(k) *Five-day report* means a medical device report that must be submitted by a manufacturer to FDA pursuant to §803.53, on FDA Form 3500A or electronic equivalent as approved under §803.14, within 5 work days.

(l) *Hospital* means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (medical, occupational, speech, physical, etc.), surgical and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (e.g., not a part of a provider of services or any other facility) or may be operated by another medical entity (e.g., under the common ownership, licensure or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.

(m) *Importer* means, for the purposes of this part, any person who imports a device into the United States and who furthers the marketing of a device

from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under paragraph (o) of this section.

(n) *Malfunction* means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in § 801.4 of this chapter.

(o) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or

(4) Is the U.S. agent of a foreign manufacturer.

(p) *Manufacturer or importer report number* means the number that uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of three parts as follows:

(1) The FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. (If the manufacturing site or the importer does not have a registration number, FDA will assign a temporary MDR reporting number until the site is officially registered. The manufacturer or importer will be informed of the temporary number.);

(2) The four-digit calendar year in which the report is submitted; and

(3) The five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear 1234567–1995–00001.)

(q) *MDR* means medical device report.

(r) *MDR reportable event* (or *reportable event*) means:

(1) An event about which user facilities become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or

(2) An event about which manufacturers or importers have received or become aware of information that reasonably suggests that one of their marketed devices:

(i) May have caused or contributed to a death or serious injury; or

(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(s) *Medical personnel*, as used in this part, means an individual who:

(1) Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;

(2) Has received a diploma or a degree in a professional or scientific discipline;

(3) Is an employee responsible for receiving medical complaints or adverse event reports; or

(4) Is a supervisor of such persons.

(t)(1) *Nursing home* means an independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:

(i) Skilled nursing care and related services for persons who require medical or nursing care;

(ii) Hospice care to the terminally ill; or

(iii) Services for the rehabilitation of the injured, disabled, or sick.

(2) A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature, or location of the medical service provided by the nursing home.

(u)(1) *Outpatient diagnostic facility* means a distinct entity that:

(i) Operates for the primary purpose of conducting medical diagnostic tests on patients;

(ii) Does not assume ongoing responsibility for patient care; and

(iii) Provides its services for use by other medical personnel. (Examples include diagnostic radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography and in-vitro testing).

(2) An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

(v)(1) *Outpatient treatment facility* means a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse.

(2) An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

(w) *Patient of the facility* means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. For the purposes of this part, the definition encompasses employees of the facility or individuals affiliated with the facility, who in the course of their duties suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

(x) *Physician's office* means a facility that operates as the office of a physician or other health care professional (e.g., dentist, chiropractor, optometrist, nurse practitioner, school nurse offices, school clinics, employee health clinics, or free-standing care units) for the primary purpose of examination, evaluation, and treatment or referral of patients. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

(y) [Reserved]

(z) *Remedial action* means, for the purposes of this subpart, any action other than routine maintenance or servicing, of a device where such action is necessary to prevent recurrence of a reportable event.

(aa) [Reserved]

(bb)(1) *Serious injury* means an injury or illness that:

(i) Is life-threatening;

(ii) Results in permanent impairment of a body function or permanent damage to body structure; or

(iii) Necessitates medical or surgical intervention to preclude permanent

impairment of a body function or permanent damage to a body structure.

(2) *Permanent* means, for purposes of this subpart, irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

(cc) *Shelf life*, as required on the manufacturer's baseline report, means the maximum time a device will remain functional from the date of manufacture until it is used in patient care. Some devices have an expiration date on their labeling indicating the maximum time they can be stored before losing their ability to perform their intended function.

(dd) [Reserved]

(ee)(1) *User facility report number* means the number that uniquely identifies each report submitted by a user facility to manufacturers and FDA. This number consists of three parts as follows:

(i) The user facility's 10-digit Health Care Financing Administration (HCFA) number (if the HCFA number has fewer than 10 digits, fill the remaining spaces with zeros);

(ii) The four-digit calendar year in which the report is submitted; and

(iii) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete number will appear as follows: 1234560000–1995–0001.)

(2) If a facility has more than one HCFA number, it must select one that will be used for all of its MDR reports. If a facility has no HCFA number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000–1995–0001) and FDA will assign a number for future use. The number assigned will be used in FDA's record of that report and in any correspondence with the user facility. All zeros should be used subsequent to the first report if the user does not receive FDA's assigned number before the next report is submitted. If a facility has multiple sites, the primary site can report centrally and use one reporting number for all sites if the primary site provides the name, address and HCFA number for each respective site.

(ff) *Work day* means Monday through Friday, excluding Federal holidays.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4118, Jan. 26, 2000; 66 FR 23156, May 8, 2001]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, in § 803.3, paragraph (n)(4) was stayed indefinitely.

§ 803.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter;

(2) Any personal, medical, and similar information (including the serial number of implanted devices), which would constitute an invasion of personal privacy under § 20.63 of this chapter. FDA will disclose to a patient who requests a report, all the information in the report concerning that patient, as provided in § 20.61 of this chapter; and

(3) Any names and other identifying information of a third party voluntarily submitting an adverse event report.

(c) FDA may not disclose the identity of a device user facility which makes a report under this part except in connection with:

(1) An action brought to enforce section 301(q) of the act, including the failure or refusal to furnish material or information required by section 519 of the act;

(2) A communication to a manufacturer of a device which is the subject of a report required by a user facility under § 803.30; or

(3) A disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.10 General description of reports required from user facilities, importers, and manufacturers.

(a) *Device user facilities.* User facilities must submit the following reports, which are described more fully in subpart C of this part.

(1) User facilities must submit MDR reports of individual adverse events within 10 days after the user facility becomes aware of an MDR reportable event as described in §§ 803.30 and 803.32.

(i) User facilities must submit reports of device-related deaths to FDA and to the manufacturer, if known.

(ii) User facilities must submit reports of device-related serious injuries to manufacturers, or to FDA, if the manufacturer is unknown.

(2) User facilities must submit annual reports as described in § 803.33.

(b) *Device importers.* Importers must submit the following reports, which are described more fully in subpart D of this part.

(1) Importers must submit MDR reports of individual adverse events within 30 days after the importer becomes aware of an MDR reportable event as described in §§ 803.40 and 803.42.

(i) Importers must submit reports of device-related deaths or serious injuries to FDA and to the manufacturer.

(ii) Importers must submit reports of malfunctions to the manufacturer.

(2) [Reserved]

(c) *Device manufacturers.* Manufacturers must submit the following reports as described more fully in subpart E of this part:

(1) MDR reports of individual adverse events within 30 days after the manufacturer becomes aware of a reportable death, serious injury, or malfunction as described in §§ 803.50 and 803.52.

(2) MDR reports of individual adverse events within 5 days of:

(i) Becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health or,

(ii) Becoming aware of an MDR reportable event for which FDA has made a written request, as described in § 803.53.

(3) Annual baseline reports as described in § 803.55.

(4) Supplemental reports if they obtain information that was not provided in an initial report as described in § 803.56.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000; 66 FR 23157, May 8, 2001]

§ 803.11 Obtaining the forms.

User facilities and manufacturers must submit all reports of individual adverse events on FDA Form 3500A (MEDWATCH form) or in an electronic equivalent as approved under § 803.14. This form and all other forms referenced in this section can also be obtained from the Consolidated Forms and Publications Office, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20875; from the Food and Drug Administration, MEDWATCH (HF–2), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7240; from the Division of Small Manufacturers Assistance, Office of Health and Industry Programs, Center for Devices and Radiological Health (HFZ–220), 1350 Piccard Dr. Rockville, MD 20850, FAX 301–443–8818; or from http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html on the Internet.

[65 FR 17136, Mar. 31, 2000]

§ 803.12 Where to submit reports.

(a) Any written report or additional information required under this part shall be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, MD 20847–3002.

(b) Each report and its envelope shall be specifically identified, e.g., ''User Facility Report,'' ''Annual Report,'' ''Importer Report,'' ''Manufacturer Report,'' ''5–Day Report,'' ''Baseline Report,'' etc.

(c) If an entity is confronted with a public health emergency, this can be brought to FDA's attention by contacting the FDA Emergency Operations Branch (HFC–162), Office of Regional Operations, at 301–443–1240, and should be followed by the submission of a FAX report to 301–443–3757.

(d) A voluntary telephone report may be submitted to, or information regarding voluntary reporting may be obtained from, the MEDWATCH hotline at 800–FDA–1088.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.13 English reporting requirement.

(a) All reports required in this part which are submitted in writing or electronic equivalent shall be submitted to FDA in English.

(b) All reports required in this part which are submitted on an electronic medium shall be submitted to FDA in a manner consistent with § 803.14.

§ 803.14 Electronic reporting.

(a) Any report required by this part may be submitted electronically with prior written consent from FDA. Such consent is revocable. Electronic report submissions include alternative reporting media (magnetic tape, disc, etc.) and computer-to-computer communication.

(b) Any electronic report meeting electronic reporting standards, guidance documents, or other procedures developed by the agency for MDR reporting will be deemed to have prior approval for use.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 56480, Sept. 19, 2000]

§ 803.15 Requests for additional information.

(a) FDA may determine that protection of the public health requires additional or clarifying information for medical device reports submitted to FDA under this part. In these instances, and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible, the agency will notify the reporting entity in writing of the additional information that is required.

(b) Any request under this section shall state the reason or purpose for which the information is being requested, specify the date that the information is to be submitted and clearly relate the request to a reported event. All verbal requests will be confirmed in writing by the agency.

§ 803.16 Disclaimers.

A report or other information submitted by a reporting entity under this part, and any release by FDA of that report or information, does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event. The reporting entity need not admit and may deny that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a reportable event.

§ 803.17 Written MDR procedures.

User facilities, importers, and manufacturers shall develop, maintain, and implement written MDR procedures for the following:

(a) Internal systems that provide for:

(1) Timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements;

(2) A standardized review process/procedure for determining when an event meets the criteria for reporting under this part; and

(3) Timely transmission of complete medical device reports to FDA and/or manufacturers;

(b) Documentation and record-keeping requirements for:

(1) Information that was evaluated to determine if an event was reportable;

(2) All medical device reports and information submitted to FDA and manufacturers;

(3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000; 66 FR 23157, May 8, 2001]

§ 803.18 Files and distributor records.

(a) User facilities, importers, and manufacturers shall establish and

maintain MDR event files. All MDR event files shall be prominently identified as such and filed to facilitate timely access.

(b)(1) For purposes of this part, ''MDR event files'' are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information, e.g., medical records, patient files, engineering reports, etc., in lieu of copying and maintaining duplicates in this file. MDR event files must contain:

(i) Information in the possession of the reporting entity or references to information related to the adverse event, including all documentation of the entity's deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part.

(ii) Copies of all MDR forms, as required by this part, and other information related to the event that was submitted to FDA and other entities (*e.g.*, an importer, distributor, or manufacturer).

(2) User facilities, importers, and manufacturers shall permit any authorized FDA employee during all reasonable times to access, to copy, and to verify the records required by this part.

(c) User facilities shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. Manufacturers and importers shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. MDR event files must be maintained for the time periods described in this paragraph even if the device is no longer distributed.

(d)(1) A device distributor shall establish and maintain device complaint records containing any incident information, including any written, electronic, or oral communication, either received by or generated by the firm, that alleges deficiencies related to the identity (*e.g.*, labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. Information regarding the evaluation of the allegations, if any, shall also be maintained in the incident record. Device incident records shall be prominently identified as such and shall be filed by device, and may be maintained in written or electronic form. Files maintained in electronic form must be backed up.

(2) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the record.

(3) A device distributor shall maintain the device complaint files established under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§ 820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

(e) The manufacturer may maintain MDR event files as part of its complaint file, under § 820.198 of this chapter, provided that such records are prominently identified as MDR reportable events. A report submitted under this subpart A shall not be considered to comply with this part unless the event has been evaluated in accordance with the requirements of § 820.198 of this chapter. MDR files shall contain an explanation of why any information required by this part was not submitted or could not be obtained. The results of the evaluation of each event are to be documented and maintained in the manufacturer's MDR event file.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000; 69 FR 11311, Mar. 10, 2004]

§ 803.19 Exemptions, variances, and alternative reporting requirements.

(a) The following persons are exempt from the reporting requirements under this part.

(1) An individual who is a licensed practitioner who prescribes or administers devices intended for use in humans and who manufactures or imports devices solely for use in diagnosing and treating persons with whom the practitioner has a ''physician-patient'' relationship.

(2) An individual who manufactures devices intended for use in humans solely for such person's use in research or teaching and not for sale, including any person who is subject to alternative reporting requirements under the investigational device exemption regulations, part 812 of this chapter, which require reporting of all adverse device effects.

(3) Dental laboratories, or optical laboratories.

(b) Manufacturers, importers, or user facilities may request exemptions or variances from any or all of the reporting requirements in this part. The request shall be in writing and include information necessary to identify the firm and device, a complete statement of the request for exemption, variance, or alternative reporting, and an explanation why the request is justified.

(c) FDA may grant in writing, to a manufacturer, importer, or user facility, an exemption, variance, or alternative from, or to, any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time period. These modifications may be initiated by a request as specified in this section, or at the discretion of FDA. When granting such modifications, FDA may impose other reporting requirements to ensure the protection of public health.

(d) FDA may revoke or modify in writing an exemption, variance, or alternative reporting requirements if FDA determines that protection of the public health justifies the modification or a return to the requirements as stated in this part.

(e) Firms granted a reporting modification by FDA shall provide any reports or information required by that approval. The conditions of the approval will replace and supersede the reporting requirement specified in this part until such time that FDA revokes or modifies the alternative reporting requirements in accordance with paragraph (d) of this section.

[60 FR 63597, Dec. 11, 1995, as amended at 61 FR 44615, Aug. 28, 1996; 65 FR 4119, Jan. 26, 2000; 65 FR 17136, Mar. 31, 2000; 66 FR 23157, May 8, 2001]

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

§ 803.20 How to report.

(a) *Description of form.* There are two versions of the MEDWATCH form for individual reports of adverse events. FDA Form 3500 is available for use by health professionals and consumers for the submission of voluntary reports regarding FDA-regulated products. FDA Form 3500A is the mandatory reporting form to be used for submitting reports by user facilities, importers, and manufacturers of FDA-regulated products. The form has some sections that must be completed by all reporters and other sections that must be completed only by the user facility, importer, or manufacturer.

(1) The front of FDA Form 3500A is to be filled out by all reporters. The front of the form requests information regarding the patient, the event, the device, and the ''initial reporter'' (*i.e.*, the first person or entity that submitted the information to the user facility, manufacturer, or importer).

(2) The back part of the form contains sections to be completed by user facilities, importers, and manufacturers. User facilities and importers must complete section F; device manufacturers must complete sections G and H. Manufacturers are not required to recopy information submitted to them on a Form 3500A unless the information is being copied onto an electronic medium. If the manufacturer corrects or supplies information missing from the other reporter's 3500A form, it should attach a copy of that form to the manufacturer's report form. If the information from the other reporter's 3500A form is complete and correct, the manufacturer can fill in the remaining information on the same form.

(b) *Reporting standards.* (1) User facilities are required to submit MDR reports to:

(i) The device manufacturer and to FDA within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death; or

(ii) The manufacturer within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. Such reports shall be submitted to FDA if the device manufacturer is not known.

(2) Importers are required to submit death and serious injury reports to FDA and the device manufacturer and submit malfunction reports to the manufacturer only:

(i) Within 30 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury.

(ii) Within 30 days of receiving information that a device marketed by the importer has malfunctioned and that such a device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(3) Manufacturers are required to submit MDR reports to FDA:

(i) Within 30 days of becoming aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(ii) Within 30 days of becoming aware of information that reasonably suggests a device has malfunctioned and that device or a similar device marketed by the manufacturer would be likely to cause a death or serious injury if the malfunction were to recur; or

(iii) Within 5 days if required by § 803.53.

(c) *Information that reasonably suggests a reportable event occurred.* (1) Information that reasonably suggests that a device has or may have caused or contributed to an MDR reportable event (i.e., death, serious injury, and, for manufacturers and importers, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur) includes any information, such as professional, scientific or medical facts and observations or opinions, that would reasonably suggest that a device has caused or may have caused or contributed to a reportable event.

(2) Entities required to report under this part do not have to report adverse events for which there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, nurse, risk manager, or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Information which leads the qualified person to determine that a device-related event is or is not reportable must be contained in the MDR event files, as described in § 803.18.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000; 66 FR 23157, May 8, 2001]

§ 803.21 Reporting codes.

(a) FDA has developed a MEDWATCH Mandatory Reporting Form Coding Manual for use with medical device reports. This manual contains codes for hundreds of adverse events for use with FDA Form 3500A. The coding manual is available from the Division of Small Manufacturer Assistance, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850, FAX 301–443–8818.

(b) FDA may use additional coding of information on the reporting forms or modify the existing codes on an ad hoc or generic basis. In such cases, FDA will ensure that the new coding information is available to all reporters.

§ 803.22 When not to file.

(a) Only one medical device report from the user facility, importer, or manufacturer is required under this part if the reporting entity becomes aware of information from multiple sources regarding the same patient and same event.

(b) A medical device report that would otherwise be required under this section is not required if:

(1) The user facility, importer, or manufacturer determines that the information received is erroneous in that a device-related adverse event did not

occur. Documentation of such reports shall be retained in MDR files for time periods specified in § 803.18.

(2) The manufacturer or importer determines that the device was manufactured or imported by another manufacturer or importer. Any reportable event information that is erroneously sent to a manufacturer or importer shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured or imported by that firm.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4120, Jan. 26, 2000]

Subpart C—User Facility Reporting Requirements

§ 803.30 Individual adverse event reports; user facilities.

(a) *Reporting standard.* A user facility shall submit the following reports to the manufacturer or to FDA, or both, as specified below:

(1) *Reports of death.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall as soon as practicable, but not later than 10 work days after becoming aware of the information, report the information required by § 803.32 to FDA, on FDA Form 3500A, or an electronic equivalent as approved under § 803.14, and if the identity of the manufacturer is known, to the device manufacturer.

(2) *Reports of serious injury.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility, the facility shall, as soon as practicable but not later than 10 work days after becoming aware of the information, report the information required by § 803.32, on FDA Form 3500A or electronic equivalent, as approved under § 803.14, to the manufacturer of the device. If the identity of the manufacturer is not known, the report shall be submitted to FDA.

(b) *Information that is reasonably known to user facilities.* User facilities must provide all information required in this subpart C that is reasonably known to them. Such information includes information found in documents in the possession of the user facility and any information that becomes available as a result of reasonable followup within the facility. A user facility is not required to evaluate or investigate the event by obtaining or evaluating information that is not reasonably known to it.

§ 803.32 Individual adverse event report data elements.

User facility reports shall contain the following information, reasonably known to them as described in 803.30(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:

(i) Life threatening injury or illness;

(ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests including dates and laboratory data; and

(7) Description of other relevant history including pre- existing medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;

(2) Type of device;
(3) Manufacturer name and address;
(4) Operator of the device (health professional, patient, lay user, other);
(5) Expiration date;
(6) Model number, catalog number, serial number, lot number, or other identifying number;
(7) Date of device implantation (month, day, year);
(8) Date of device explantation (month, day, year);
(9) Whether device was available for evaluation and whether device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and
(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)
(d) Initial reporter information (Block E) shall contain the following:
(1) Name, address, and telephone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;
(2) Whether the initial reporter is a health professional;
(3) Occupation; and
(4) Whether initial reporter also sent a copy of the report to FDA, if known.
(e) User facility information (Block F) shall contain the following:
(1) Whether reporter is a user facility;
(2) User facility number;
(3) User facility address;
(4) Contact person;
(5) Contact person's telephone number;
(6) Date the user facility became aware of the event (month, day, year);
(7) Type of report (initial or followup (if followup, include report number of initial report));
(8) Date of the user facility report (month, day, year);
(9) Approximate age of device;
(10) Event problem codes—patient code and device code (refer to FDA ''Coding Manual For Form 3500A'');
(11) Whether a report was sent to FDA and the date it was sent (month, day, year);
(12) Location, where event occurred;
(13) Whether report was sent to the manufacturer and the date it was sent (month, day, year); and
(14) Manufacturer name and address; if available.

§ 803.33 Annual reports.

(a) Each user facility shall submit to FDA an annual report on FDA Form 3419, or electronic equivalent as approved by FDA under § 803.14. Annual reports shall be submitted by January 1 of each year. The annual report and envelope shall be clearly identified and submitted to FDA with information that includes:
(1) User facility's HCFA provider number used for medical device reports, or number assigned by FDA for reporting purposes in accordance with § 803.3(ee);
(2) Reporting year;
(3) Facility's name and complete address;
(4) Total number of reports attached or summarized;
(5) Date of the annual report and the lowest and highest user facility report number of medical device reports submitted during the report period, e.g., 1234567890–1995–0001 through 1000;
(6) Name, position title, and complete address of the individual designated as the facility contact person responsible for reporting to FDA and whether that person is a new contact for that facility; and
(7) Information for each reportable event that occurred during the annual reporting period including:
(i) User facility report number;
(ii) Name and address of the device manufacturer;
(iii) Device brand name and common name;
(iv) Product model, catalog, serial and lot number;
(v) A brief description of the event reported to the manufacturer and/or FDA; and
(vi) Where the report was submitted, i.e., to FDA, manufacturer, distributor, importer, etc.
(b) In lieu of submitting the information in paragraph (a)(7) of this section, a user facility may submit a copy of FDA Form 3500A, or an electronic equivalent as approved under section 803.14, for each medical device report submitted to FDA and/or manufacturers by that facility during the reporting period.

(c) If no reports are submitted to either FDA or manufacturers during these time periods, no annual report is required.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4120, Jan. 26, 2000]

Subpart D—Importer Reporting Requirements

SOURCE: 65 FR 4120, Jan. 26, 2000, unless otherwise noted.

§ 803.40 Individual adverse event reporting requirements; importers.

(a) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 803.42 on FDA form 3500A as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

(b) An importer shall submit to the manufacturer a report containing information required by § 803.42 on FDA form 3500A, as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the importer's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

§ 803.42 Individual adverse event report data elements.

Individual medical device importer reports shall contain the following information, in so far as the information is known or should be known to the importer, as described in § 803.40, which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Adverse event or product problem;

(2) Outcomes attributed to the adverse event, that is:

(i) Death;

(ii) Life threatening injury or illness;

(iii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iv) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of the event or problem to include a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Other relevant patient history including preexisting medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;

(2) Type of device;

(3) Manufacturer name and address;

(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)

(d) Initial reporter information (Block E) shall contain the following:

(1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to FDA, if known.

(e) Importer information (Block F) shall contain the following:

(1) Whether reporter is an importer;

(2) Importer report number;

(3) Importer address;

(4) Contact person;

(5) Contact person's telephone number;

(6) Date the importer became aware of the event (month, day, year);

(7) Type of report (initial or followup (if followup, include report number of initial report));

(8) Date of the importer report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to FDA ''Coding Manual For Form 3500A'');

(11) Whether a report was sent to FDA and the date it was sent (month, day, year);

(12) Location, where event occurred;

(13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and

(14) Manufacturer name and address; if available.

Subpart E—Manufacturer Reporting Requirements

§ 803.50 Individual adverse event reports; manufacturers.

(a) *Reporting standards.* Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:

(1) May have caused or contributed to a death or serious injury; or

(2) Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) *Information that is reasonably known to manufacturers.* (1) Manufacturers must provide all information required in this subpart E that is reasonably known to them. FDA considers the following information to be reasonably known to the manufacturer:

(i) Any information that can be obtained by contacting a user facility, importer, or other initial reporter;

(ii) Any information in a manufacturer's possession; or

(iii) Any information that can be obtained by analysis, testing or other evaluation of the device.

(2) Manufacturers are responsible for obtaining and providing FDA with information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. Manufacturers are also responsible for conducting an investigation of each event and evaluating the cause of the event. If a manufacturer cannot provide complete information on an MDR report, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information. Any required information not available at the time of the report, which is obtained after the initial filing, must be provided by the manufacturer in a supplemental report under § 803.56.

[60 FR 63597, Dec. 11, 1995, as amended at 66 FR 23157, May 8, 2001]

§ 803.52 Individual adverse event report data elements.

Individual medical device manufacturer reports shall contain the following information, known or reasonably known to them as described in § 803.50(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Adverse event or product problem;

(2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:

(i) Life threatening injury or illness;

(ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of the event or problem to include a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Other relevant patient history including pre-existing medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;

(2) Type of device;

(3) Manufacturer name and address;

(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)

(d) Initial reporter information (Block E) shall contain the following:

(1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or importer;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to FDA, if known.

(e) All manufacturers (Block G) shall contain the following:

(1) Contact office name and address and device manufacturing site;

(2) Telephone number;

(3) Report sources;

(4) Date received by manufacturer (month, day, year);

(5) Type of report being submitted (e.g., 5-day, initial, supplemental); and

(6) Manufacturer report number.

(f) Device manufacturers (Block H) shall contain the following:

(1) Type of reportable event (death, serious injury, malfunction, etc.);

(2) Type of followup report, if applicable (e.g., correction, response to FDA request, etc.);

(3) If the device was returned to the manufacturer and evaluated by the manufacturer, a summary of the evaluation. If no evaluation was performed, provide an explanation why no evaluation was performed;

(4) Device manufacture date (month, day, year);

(5) Was device labeled for single use;

(6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA ''Coding Manual for Form 3500A'');

(7) Whether remedial action was taken and type;

(8) Whether use of device was initial, reuse, or unknown;

(9) Whether remedial action was reported as a removal or correction under section 519(f) of the act (list the correction/removal report number); and

(10) Additional manufacturer narrative; and/or

(11) Corrected data, including:

(i) Any information missing on the user facility report or importer report, including missing event codes, or information corrected on such forms after manufacturer verification;

(ii) For each event code provided by the user facility under § 803.32(e)(10) or the importer under § 803.42(e)(10), a statement of whether the type of event represented by the code is addressed in the device labeling; and

(iii) If any required information was not provided, an explanation of why such information was not provided and the steps taken to obtain such information.

[60 FR 63597, Dec. 11, 1995, as amended at 66 FR 23157, May 8, 2001]

§ 803.53 Five-day reports.

A manufacturer shall submit a 5-day report to FDA, on Form 3500A or electronic equivalent as approved by FDA under § 803.14 within 5 workdays of:

(a) Becoming aware that a reportable MDR event or events, from any information, including any trend analysis, necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health; or

(b) Becoming aware of an MDR reportable event for which FDA has made a written request for the submission of a 5-day report. When such a request is made, the manufacturer shall submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. The time period stated in the original written request can be extended by FDA if it is in the interest of the public health.

§ 803.55 Baseline reports.

(a) A manufacturer shall submit a baseline report on FDA Form 3417, or electronic equivalent as approved by FDA under § 803.14 for a device when the device model is first reported under § 803.50.

(b) Each baseline report shall be updated annually, on the anniversary month of the initial submission, after the initial baseline report is submitted. Changes to baseline information shall be reported in the manner described in § 803.56 (i.e., include only the new, changed, or corrected information in the appropriate portion(s) of the report form). Baseline reports shall contain the following:

(1) Name, complete address, and registration number of the manufacturer's reporting site. If the reporting site is not registered, FDA will assign a temporary registration number until the reporting site officially registers. The manufacturer will be informed of the temporary registration number;

(2) FDA registration number of each site where the device is manufactured;

(3) Name, complete address, and telephone number of the individual who has been designated by the manufacturer as its MDR contact and date of the report. For foreign manufacturers, a confirmation that the individual submitting the report is the agent of the manufacturer designated under § 803.58(a) is required;

(4) Product identification, including device family, brand name, generic name, model number, catalog number, product code and any other product identification number or designation;

(5) Identification of any device previously reported in a baseline report that is substantially similar (e.g., same device with a different model number, or same device except for cosmetic differences in color or shape) to the device being reported, including the identification of the previously reported device by model number, catalog number or other product identification, and the date of the baseline report for the previously reported device;

(6) Basis for marketing, including 510(k) premarket notification number or PMA number, if applicable, and whether the device is currently the subject of an approved post-market study under section 522 of the act;

(7) Date the device was initially marketed and, if applicable, the date on which the manufacturer ceased marketing the device;

(8) Shelf life, if applicable, and expected life of the device;

(9) The number of devices manufactured and distributed in the last 12 months and, an estimate of the number of devices in current use; and

(10) Brief description of any methods used to estimate the number of devices distributed and the method used to estimate the number of devices in current use. If this information was provided in a previous baseline report, in lieu of resubmitting the information, it may be referenced by providing the date and product identification for the previous baseline report.

EFFECTIVE DATE NOTE: At 61 FR 39869, July 31, 1996, in § 803.55, paragraphs (b)(9) and (10) were stayed indefinitely.

§ 803.56 Supplemental reports.

When a manufacturer obtains information required under this part that was not provided because it was not known or was not available when the initial report was submitted, the manufacturer shall submit to FDA the supplemental information within 1 month

following receipt of such information. In supplemental reports, the manufacturer shall:

(a) Indicate on the form and the envelope, that the reporting form being submitted is a supplemental report. If the report being supplemented is an FDA Form 3500A report, the manufacturer must select, in Item H–2, the appropriate code for the type of supplemental information being submitted;

(b) Provide the appropriate identification numbers of the report that will be updated with the supplemental information, e.g., original manufacturer report number and user facility report number, if applicable;

(c) For reports that cross reference previous reports, include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s).

§ 803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and § 807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of § 803.50;

(3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(4) Maintain complaint files in accordance with § 803.18; and

(5) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

[60 FR 63597, Dec. 11, 1995, as amended at 66 FR 23157, May 8, 2001]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, § 803.58 was stayed indefinitely.

EFFECTIVE DATE NOTE: At 70 FR 9519, Feb. 28, 2005, part 803 was revised effective July 13, 2005. For the convience of the user, the revised text is set forth as follows:

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

Subpart C—User Facility Reporting Requirements

AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

Subpart A—General Provisions

§ 803.1 What does this part cover?

(a) This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified followup and baseline reports. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use. If you are a medical device distributor, you must maintain records (files) of incidents, but you are not required to report these incidents.

(b) This part supplements and does not supersede other provisions of this chapter, including the provisions of part 820 of this chapter.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 803.3 How does FDA define the terms used in this part?

Some of the terms we use in this part are specific to medical device reporting and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation of the law. This section defines the following terms as used in this part:

Act means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, as amended.

Ambulatory surgical facility (ASF) means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

Become aware means that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.

(1) If you are a device user facility, you are considered to have ''become aware'' when medical personnel, as defined in this section, who are employed by or otherwise formally affiliated with your facility, obtain information about a reportable event.

(2) If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with §803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

(3) If you are an importer, you are considered to have become aware of an event when any of your employees becomes aware of a

reportable event that is required to be reported by you within 30 days.

Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

(1) Failure;

(2) Malfunction;

(3) Improper or inadequate design;

(4) Manufacture;

(5) Labeling; or

(6) User error.

Device family. (1) Device family means a group of one or more devices manufactured by or for the same manufacturer and having the same:

(i) Basic design and performance characteristics related to device safety and effectiveness,

(ii) Intended use and function, and

(iii) Device classification and product code.

(2) You may consider devices that differ only in minor ways not related to safety or effectiveness to be in the same device family. When grouping products in device families, you may consider factors such as brand name and common name of the device and whether the devices were introduced into commercial distribution under the same 510(k) or premarket approval application (PMA).

Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this section, which is not a physician's office, as defined in this section. School nurse offices and employee health units are not device user facilities.

Distributor means any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.

Expected life of a device means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified ''end of life'' (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time.

FDA, we, or us means the Food and Drug Administration.

Five-day report means a medical device report that must be submitted by a manufacturer to us under §803.53, on FDA Form 3500A or an electronic equivalent approved under §803.14, within 5 work days.

Hospital means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (such as medical, occupational, speech, physical), surgical, and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (e.g., not a part of a provider of services or any other facility) or may be operated by another medical entity (e.g., under the common ownership, licensure, or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.

Importer means any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.

Malfunction means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in §801.4 of this chapter.

Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;

(3) Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or

(4) Is the U.S. agent of a foreign manufacturer.

Manufacturer or importer report number. Manufacturer or importer report number means the number that uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of the following three parts:

(1) The FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. If the manufacturing site or the importer does not have an establishment registration number, we will assign a temporary MDR reporting number until the site is registered in accordance with part 807 of this chapter. We will inform the manufacturer or importer of the temporary MDR reporting number;

(2) The four-digit calendar year in which the report is submitted; and

(3) The five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear as follows: 1234567–1995–00001.)

MDR means medical device report.

MDR reportable event (or reportable event) means:

(1) An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or

(2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:

(i) May have caused or contributed to a death or serious injury, or

(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Medical personnel means an individual who:

(1) Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;

(2) Has received a diploma or a degree in a professional or scientific discipline;

(3) Is an employee responsible for receiving medical complaints or adverse event reports; or

(4) Is a supervisor of these persons.

Nursing home means:

(1) An independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:

(i) Skilled nursing care and related services for persons who require medical or nursing care;

(ii) Hospice care to the terminally ill; or

(iii) Services for the rehabilitation of the injured, disabled, or sick.

(2) A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature or location of the medical service provided by the nursing home.

Outpatient diagnostic facility. (1) Outpatient diagnostic facility means a distinct entity that:

(i) Operates for the primary purpose of conducting medical diagnostic tests on patients,

(ii) Does not assume ongoing responsibility for patient care, and

(iii) Provides its services for use by other medical personnel.

(2) Outpatient diagnostic facilities include outpatient facilities providing radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in vitro testing. An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

Outpatient treatment facility means a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or in a home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include the following: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse. An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

Patient of the facility means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. This includes

employees of the facility or individuals affiliated with the facility who, in the course of their duties, suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

Physician's office means a facility that operates as the office of a physician or other health care professional for the primary purpose of examination, evaluation, and treatment or referral of patients. Examples of physician offices include dentist offices, chiropractor offices, optometrist offices, nurse practitioner offices, school nurse offices, school clinics, employee health clinics, or freestanding care units. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

Remedial action means any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.

Serious injury means an injury or illness that:

(1) Is life-threatening,

(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

Shelf life means the maximum time a device will remain functional from the date of manufacture until it is used in patient care. Some devices have an expiration date on their labeling indicating the maximum time they can be stored before losing their ability to perform their intended function.

User facility report number means the number that uniquely identifies each report submitted by a user facility to manufacturers and to us. This number consists of the following three parts:

(1) The user facility's 10-digit Centers for Medicare and Medicaid Services (CMS) number (if the CMS number has fewer than 10 digits, fill the remaining spaces with zeros);

(2) The four-digit calendar year in which the report is submitted; and

(3) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete user facility report number will appear as follows: 1234560000–2004–0001. If a user facility has more than one CMS number, it must select one that will be used for all of its MDR reports. If a user facility has no CMS number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000–2004–0001). We will assign a number for future use and send that number to the user facility. This number is used in our record of the initial report, in subsequent reports, and in any correspondence with the user facility. If a facility has multiple sites, the primary site may submit reports for all sites and use one reporting number for all sites if the primary site provides the name, address, and CMS number for each respective site.)

Work day means Monday through Friday, except Federal holidays.

§ 803.9 What information from the reports do we disclose to the public?

(a) We may disclose to the public any report, including any FDA record of a telephone report, submitted under this part. Our disclosures are governed by part 20 of this chapter.

(b) Before we disclose a report to the public, we will delete the following:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter;

(2) Any personal, medical, and similar information, including the serial number of implanted devices, which would constitute an invasion of personal privacy under § 20.63 of this chapter. However, if a patient requests a report, we will disclose to that patient all the information in the report concerning that patient, as provided in § 20.61 of this chapter; and

(3) Any names and other identifying information of a third party that voluntarily submitted an adverse event report.

(c) We may not disclose the identity of a device user facility that makes a report under this part except in connection with:

(1) An action brought to enforce section 301(q) of the act, including the failure or refusal to furnish material or information required by section 519 of the act;

(2) A communication to a manufacturer of a device that is the subject of a report required to be submitted by a user facility under § 803.30; or

(3) A disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

§ 803.10 Generally, what are the reporting requirements that apply to me?

(a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows:

(1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths to us and to the manufacturer, if known; or

(ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.

(2) Submit annual reports (described in § 803.33) to us.

(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or

(ii) Submit reports of device-related malfunctions to the manufacturer.

(2) [Reserved]

(c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.

(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:

(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or

(ii) A reportable event for which we made a written request.

(3) Submit annual baseline reports.

(4) Submit supplemental reports if you obtain information that you did not submit in an initial report.

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

If you are a user facility, importer, or manufacturer, you must submit all reports of individual adverse events on FDA MEDWATCH Form 3500A or in an electronic equivalent as approved under § 803.14. You may obtain this form and all other forms referenced in this section from any of the following:

(1) The Consolidated Forms and Publications Office, Beltsville Service Center, 6351 Ammendale Rd., Landover, MD 20705;

(2) FDA, MEDWATCH (HF–2), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7240;

(3) Division of Small Manufacturers, International, and Consumer Assistance, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health (CDRH) (HFZ–220), 1350 Piccard Dr. Rockville, MD 20850, by e-mail: *DSMICA@CDRH.FDA.GOV*, or FAX: 301–443–8818; or

(4) On the Internet at *http://www.fda.gov/cdrh/mdr/mdr-forms.html*.

§ 803.12 Where and how do I submit reports and additional information?

(a) You must submit any written report or additional information required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847–3002.

(b) You must specifically identify each report (e.g., ''User Facility Report,'' ''Annual Report,'' ''Importer Report,'' ''Manufacturer Report,'' ''10-Day Report'').

(c) If you have a public health emergency, you can alert the FDA Emergency Operations Branch (HFC–162), Office of Regional Operations, at 301–443–1240. After contacting us, you should submit a FAX report to 301–443–3757.

(d) You may submit a voluntary telephone report to the MEDWATCH office at 800–FDA–1088. You may also obtain information regarding voluntary reporting from the MEDWATCH office at 800–FDA–1088. You may also find the voluntary MEDWATCH 3500 form and instructions to complete it at *http://www.fda.gov/medwatch/getforms.htm*.

§ 803.13 Do I need to submit reports in English?

(a) Yes. You must submit all written or electronic equivalent reports required by this part in English.

(b) If you submit any reports required by this part in an electronic medium, that submission must be done in accordance with § 803.14.

§ 803.14 How do I submit a report electronically?

(a) You may electronically submit any report required by this part if you have our prior written consent. We may revoke this consent at anytime. Electronic report submissions include alternative reporting media (magnetic tape, disc, etc.) and computer-to-computer communication.

(b) If your electronic report meets electronic reporting standards, guidance documents, or other MDR reporting procedures that we have developed, you may submit the report electronically without receiving our prior written consent.

§ 803.15 How will I know if you require more information about my medical device report?

(a) We will notify you in writing if we require additional information and will tell you what information we need. We will require additional information if we determine that protection of the public health requires additional or clarifying information for medical device reports submitted to us and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible to us.

(b) In any request under this section, we will state the reason or purpose for the information request, specify the due date for submitting the information, and clearly identify the reported event(s) related to our request. If we verbally request additional information, we will confirm the request in writing.

§ 803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?

No. A report or other information submitted by you, and our release of that report or information, is not necessarily an admission that the device, or you or your employees, caused or contributed to the reportable event. You do not have to admit and may deny that the report or information submitted under this part constitutes an admission that the device, you, or your employees, caused or contributed to a reportable event.

§ 803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?

If you are a user facility, importer, or manufacturer, you must develop, maintain, and implement written MDR procedures for the following:

(a) Internal systems that provide for:

(1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;

(2) A standardized review process or procedure for determining when an event meets the criteria for reporting under this part; and

(3) Timely transmission of complete medical device reports to manufacturers or to us, or to both if required.

(b) Documentation and recordkeeping requirements for:

(1) Information that was evaluated to determine if an event was reportable;

(2) All medical device reports and information submitted to manufacturers and/or us;

(3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by us.

§ 803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?

(a) If you are a user facility, importer, or manufacturer, you must establish and maintain MDR event files. You must clearly identify all MDR event files and maintain them to facilitate timely access.

(b)(1) For purposes of this part, ''MDR event files'' are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information (e.g., medical records, patient files, engineering reports), in lieu of copying and maintaining duplicates in this file. Your MDR event files must contain:

(i) Information in your possession or references to information related to the adverse event, including all documentation of your deliberations and decisionmaking processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part; and

(ii) Copies of all MDR forms, as required by this part, and other information related to the event that you submitted to us and other entities such as an importer, distributor, or manufacturer.

(2) If you are a user facility, importer, or manufacturer, you must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.

(c) If you are a user facility, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. If you are a manufacturer or importer, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. If the device is no longer distributed, you still must maintain MDR event files for the time periods described in this paragraph.

(d)(1) If you are a device distributor, you must establish and maintain device complaint records (files). Your records must contain any incident information, including any written, electronic, or oral communication, either received or generated by you, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. You must also maintain information about your evaluation of the allegations, if any, in the incident record. You must clearly identify the records as device incident records and file these records by device name. You may maintain these records in written or electronic format. You must back up any file maintained in electronic format.

(2) You must retain copies of the required device incident records for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater. You must maintain copies of these records for this period even if you no longer distribute the device.

(3) You must maintain the device complaint files established under this section at your principal business establishment. If you are also a manufacturer, you may maintain the file at the same location as you maintain your complaint file under part 820 of this chapter. You must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.

(e) If you are a manufacturer, you may maintain MDR event files as part of your complaint file, under part 820 of this chapter, if you prominently identify these records as MDR reportable events. We will not consider your submitted MDR report to comply with

this part unless you evaluate an event in accordance with the quality system requirements described in part 820 of this chapter. You must document and maintain in your MDR event files an explanation of why you did not submit or could not obtain any information required by this part, as well as the results of your evaluation of each event.

§ 803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

(a) We exempt the following persons from the adverse event reporting requirements in this part:

(1) A licensed practitioner who prescribes or administers devices intended for use in humans and manufactures or imports devices solely for use in diagnosing and treating persons with whom the practitioner has a ''physician-patient'' relationship;

(2) An individual who manufactures devices intended for use in humans solely for this person's use in research or teaching and not for sale. This includes any person who is subject to alternative reporting requirements under the investigational device exemption regulations (described in part 812 of this chapter), which require reporting of all adverse device effects; and

(3) Dental laboratories or optical laboratories.

(b) If you are a manufacturer, importer, or user facility, you may request an exemption or variance from any or all of the reporting requirements in this part. You must submit the request to us in writing. Your request must include information necessary to identify you and the device; a complete statement of the request for exemption, variance, or alternative reporting; and an explanation why your request is justified.

(c) If you are a manufacturer, importer, or user facility, we may grant in writing an exemption or variance from, or alternative to, any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually or other appropriate time period. We may grant these modifications in response to your request, as described in paragraph (b) of this section, or at our discretion. When we grant modifications to the reporting requirements, we may impose other reporting requirements to ensure the protection of public health.

(d) We may revoke or modify in writing an exemption, variance, or alternative reporting requirement if we determine that revocation or modification is necessary to protect the public health.

(e) If we grant your request for a reporting modification, you must submit any reports or information required in our approval of the modification. The conditions of the approval will replace and supersede the regular reporting requirement specified in this part until such time that we revoke or modify the alternative reporting requirements in accordance with paragraph (d) of this section.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

§ 803.20 How do I complete and submit an individual adverse event report?

(a) What form must I complete and submit? There are two versions of the MEDWATCH form for individual reports of adverse events. If you are a health professional or consumer, you may use the FDA Form 3500 to submit voluntary reports regarding FDA-regulated products. If you are a user facility, importer, or manufacturer, you must use the FDA Form 3500A to submit mandatory reports about FDA-regulated products.

(1) If you are a user facility, importer, or manufacturer, you must complete the applicable blocks on the front of FDA Form 3500A. The front of the form is used to submit information about the patient, the event, the device, and the ''initial reporter'' (i.e., the first person or entity who reported the information to you).

(2) If you are a user facility, importer, or manufacturer, you must complete the applicable blocks on the back of the form. If you are a user facility or importer, you must complete block F. If you are a manufacturer, you must complete blocks G and H. If you are a manufacturer, you do not have to recopy information that you received on a Form 3500A unless you are copying the information onto an electronic medium. If you are a manufacturer and you are correcting or supplying information that is missing from another reporter's Form 3500A, you must attach a copy of that form to your report form. If you are a manufacturer and the information from another reporter's Form 3500A is complete and correct, you may fill in the remaining information on the same form and submit it to us.

(b) To whom must I submit reports and when?

(1) If you are a user facility, you must submit MDR reports to:

(i) The manufacturer and to us no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death; or

(ii) The manufacturer no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. If the manufacturer is not known, you must submit this report to us.

(2) If you are an importer, you must submit MDR reports to:

(i) The manufacturer and to us, no later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or

(ii) The manufacturer, no later than 30 days calendar after receiving information that a device you market has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(3) If you are a manufacturer, you must submit MDR reports to us:

(i) No later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(ii) No later than 30 calendar days after the day that you become aware of information that reasonably suggests a device has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; or

(iii) Within 5 work days if required by §803.53.

(c) What kind of information reasonably suggests that a reportable event has occurred?

(1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(2) If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files (described in §803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.

§803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

(a) The MEDWATCH Medical Device Reporting Code Instruction Manual contains adverse event codes for use with FDA Form 3500A. You may obtain the coding manual from CDRH's Web site at *http://www.fda.gov/cdrh/mdr/373.html*; and from the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850, FAX: 301–443–8818, or e-mail to *DSMICA@CDRH.FDA.GOV*.

(b) We may sometimes use additional coding of information on the reporting forms or modify the existing codes. If we do make modifications, we will ensure that we make the new coding information available to all reporters.

§803.22 What are the circumstances in which I am not required to file a report?

(a) If you become aware of information from multiple sources regarding the same patient and same reportable event, you may submit one medical device report.

(b) You are not required to submit a medical device report if:

(1) You are a user facility, importer, or manufacturer, and you determine that the information received is erroneous in that a device-related adverse event did not occur. You must retain documentation of these reports in your MDR files for the time periods specified in §803.18.

(2) You are a manufacturer or importer and you did not manufacture or import the device about which you have adverse event information. When you receive reportable event information in error, you must forward this information to us with a cover letter explaining that you did not manufacture or import the device in question.

Subpart C—User Facility Reporting Requirements

§803.30 If I am a user facility, what reporting requirements apply to me?

(a) You must submit reports to the manufacturer or to us, or both, as specified below:

(1) *Reports of death.* You must submit a report to us as soon as practicable but no more than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of your facility. You must also submit the report to the device manufacturer, if known. You must report information required by §803.32 on FDA Form 3500A or an electronic equivalent approved under §803.14.

(2) *Reports of serious injury.* You must submit a report to the manufacturer of the device no later than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of your facility. If the manufacturer is not known, you must submit the report to us. You must report information required by §803.32 on

FDA Form 3500A or an electronic equivalent approved under §803.14.

(b) What information does FDA consider ''reasonably known'' to me? You must submit all information required in this subpart C that is reasonably known to you. This information includes information found in documents that you possess and any information that becomes available as a result of reasonable followup within your facility. You are not required to evaluate or investigate the event by obtaining or evaluating information that you do not reasonably know.

§803.32 If I am a user facility, what information must I submit in my individual adverse event reports?

You must include the following information in your report, if reasonably known to you, as described in §803.30(b). These types of information correspond generally to the elements of FDA Form 3500A:

(a) Patient information (Form 3500A, Block A). You must submit the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Form 3500A, Block B). You must submit the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:

(i) Life-threatening injury or illness;

(ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Description of other relevant history, including preexisting medical conditions.

(c) Device information (Form 3500A, Block D). You must submit the following:

(1) Brand name;

(2) Type of device;

(3) Manufacturer name and address;

(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number, or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) Whether the device was available for evaluation and whether the device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

(d) Initial reporter information (Form 3500A, Block E). You must submit the following:

(1) Name, address, and telephone number of the reporter who initially provided information to you, or to the manufacturer or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to us, if known.

(e) User facility information (Form 3500A, Block F). You must submit the following:

(1) An indication that this is a user facility report (by marking the user facility box on the form);

(2) Your user facility number;

(3) Your address;

(4) Your contact person;

(5) Your contact person's telephone number;

(6) Date that you became aware of the event (month, day, year);

(7) Type of report (initial or followup); if it is a followup, you must include the report number of the initial report;

(8) Date of your report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to the ''MEDWATCH Medical Device Reporting Code Instructions'');

(11) Whether a report was sent to us and the date it was sent (month, day, year);

(12) Location where the event occurred;

(13) Whether the report was sent to the manufacturer and the date it was sent (month, day, year); and

(14) Manufacturer name and address, if available.

§803.33 If I am a user facility, what must I include when I submit an annual report?

(a) You must submit to us an annual report on FDA Form 3419, or electronic equivalent as approved by us under §803.14. You must submit an annual report by January 1, of each year. You must clearly identify your annual report as such. Your annual report must include:

(1) Your CMS provider number used for medical device reports, or the number assigned by us for reporting purposes in accordance with §803.3;
(2) Reporting year;
(3) Your name and complete address;
(4) Total number of reports attached or summarized;
(5) Date of the annual report and report numbers identifying the range of medical device reports that you submitted during the report period (e.g., 1234567890–2004–0001 through 1000);
(6) Name, position title, and complete address of the individual designated as your contact person responsible for reporting to us and whether that person is a new contact for you; and
(7) Information for each reportable event that occurred during the annual reporting period including:
(i) Report number;
(ii) Name and address of the device manufacturer;
(iii) Device brand name and common name;
(iv) Product model, catalog, serial and lot number;
(v) A brief description of the event reported to the manufacturer and/or us; and
(vi) Where the report was submitted, i.e., to the manufacturer, importer, or us.
(b) In lieu of submitting the information in paragraph (a)(7) of this section, you may submit a copy of FDA Form 3500A, or an electronic equivalent approved under §803.14, for each medical device report that you submitted to the manufacturers and/or to us during the reporting period.
(c) If you did not submit any medical device reports to manufacturers or us during the time period, you do not need to submit an annual report.

Subpart D—Importer Reporting Requirements

§803.40 If I am an importer, what kinds of individual adverse event reports must I submit, when must I submit them, and to whom must I submit them?

(a) *Reports of deaths or serious injuries.* You must submit a report to us, and a copy of this report to the manufacturer, as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of your marketed devices may have caused or contributed to a death or serious injury. This report must contain the information required by §803.42, on FDA form 3500A or an electronic equivalent approved under §803.14.
(b) *Reports of malfunctions.* You must submit a report to the manufacturer as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or through your own research, testing, evaluation, servicing, or maintenance of one of your devices, that reasonably suggests that one of your devices has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. This report must contain information required by §803.42, on FDA form 3500A or an electronic equivalent approved under §803.14.

§803.42 If I am an importer, what information must I submit in my individual adverse event reports?

You must include the following information in your report, if the information is known or should be known to you, as described in §803.40. These types of information correspond generally to the format of FDA Form 3500A:
(a) Patient information (Form 3500A, Block A). You must submit the following:
(1) Patient name or other identifier;
(2) Patient age at the time of event, or date of birth;
(3) Patient gender; and
(4) Patient weight.
(b) Adverse event or product problem (Form 3500A, Block B). You must submit the following:
(1) Identification of adverse event or product problem;
(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:
(i) Life-threatening injury or illness;
(ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
(iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
(3) Date of event;
(4) Date of report by the initial reporter;
(5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;
(6) Description of relevant tests, including dates and laboratory data; and
(7) Description of other relevant patient history, including preexisting medical conditions.
(c) Device information (Form 3500A, Block D). You must submit the following:
(1) Brand name;
(2) Type of device;
(3) Manufacturer name and address;
(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;
(6) Model number, catalog number, serial number, lot number, or other identifying number;
(7) Date of device implantation (month, day, year);
(8) Date of device explanation (month, day, year);
(9) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and
(10) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)
(d) Initial reporter information (Form 3500A, Block E). You must submit the following:
(1) Name, address, and telephone number of the reporter who initially provided information to the manufacturer, user facility, or distributor;
(2) Whether the initial reporter is a health professional;
(3) Occupation; and
(4) Whether the initial reporter also sent a copy of the report to us, if known.
(e) Importer information (Form 3500A, Block F). You must submit the following:
(1) An indication that this is an importer report (by marking the importer box on the form);
(2) Your importer report number;
(3) Your address;
(4) Your contact person;
(5) Your contact person's telephone number;
(6) Date that you became aware of the event (month, day, year);
(7) Type of report (initial or followup). If it is a followup report, you must include the report number of your initial report;
(8) Date of your report (month, day, year);
(9) Approximate age of device;
(10) Event problem codes—patient code and device code (refer to FDA MEDWATCH Medical Device Reporting Code Instructions);
(11) Whether a report was sent to us and the date it was sent (month, day, year);
(12) Location where event occurred;
(13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and
(14) Manufacturer name and address, if available.

Subpart E—Manufacturer Reporting Requirements

§ 803.50 If I am a manufacturer, what reporting requirements apply to me?

(a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:
(1) May have caused or contributed to a death or serious injury; or
(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.
(b) What information does FDA consider ''reasonably known'' to me?
(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:
(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;
(ii) Any information in your possession; or
(iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.
(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.
(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under § 803.56.

§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

You must include the following information in your reports, if known or reasonably known to you, as described in § 803.50(b). These types of information correspond generally to the format of FDA Form 3500A:
(a) Patient information (Form 3500A, Block A). You must submit the following:
(1) Patient name or other identifier;
(2) Patient age at the time of event, or date of birth;
(3) Patient gender; and
(4) Patient weight.
(b) Adverse event or product problem (Form 3500A, Block B). You must submit the following:
(1) Identification of adverse event or product problem;
(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:
(i) Life-threatening injury or illness;
(ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Other relevant patient history including preexisting medical conditions.

(c) Device information (Form 3500A, Block D). You must submit the following:

(1) Brand name;

(2) Type of device;

(3) Your name and address;

(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number, or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) Whether the device was available for evaluation, and whether the device was returned to you, and if so, the date it was returned to you; and

(10) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

(d) Initial reporter information (Form 3500A, Block E). You must submit the following:

(1) Name, address, and phone number of the reporter who initially provided information to you, or to the user facility or importer;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to us, if known.

(e) Reporting information for all manufacturers (Form 3500A, Block G). You must submit the following:

(1) Your reporting office's contact name and address and device manufacturing site;

(2) Your telephone number;

(3) Your report sources;

(4) Date received by you (month, day, year);

(5) Type of report being submitted (e.g., 5-day, initial, followup); and

(6) Your report number.

(f) Device manufacturer information (Form 3500A, Block H). You must submit the following:

(1) Type of reportable event (death, serious injury, malfunction, etc.);

(2) Type of followup report, if applicable (e.g., correction, response to FDA request, etc);

(3) If the device was returned to you and evaluated by you, you must include a summary of the evaluation. If you did not perform an evaluation, you must explain why you did not perform an evaluation;

(4) Device manufacture date (month, day, year);

(5) Whether the device was labeled for single use;

(6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA MEDWATCH Medical Device Reporting Code Instructions);

(7) Whether remedial action was taken and the type of action;

(8) Whether the use of the device was initial, reuse, or unknown;

(9) Whether remedial action was reported as a removal or correction under section 519(f) of the act, and if it was, provide the correction/removal report number; and

(10) Your additional narrative; and/or

(11) Corrected data, including:

(i) Any information missing on the user facility report or importer report, including any event codes that were not reported, or information corrected on these forms after your verification;

(ii) For each event code provided by the user facility under §803.32(e)(10) or the importer under 803.42(e)(10), you must include a statement of whether the type of the event represented by the code is addressed in the device labeling; and

(iii) If your report omits any required information, you must explain why this information was not provided and the steps taken to obtain this information.

§803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?

You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under §803.14, no later than 5 work days after the day that you become aware that:

(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or

(b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if

we determine it is in the interest of the public health.

§ 803.55 If I am a manufacturer, in what circumstances must I submit a baseline report, and what are the requirements for such a report?

(a) You must submit a baseline report for a device when you submit the first report under §803.50 involving that device model. Submit this report on FDA Form 3417 or an electronic equivalent approved under §803.14.

(b) You must update each baseline report annually on the anniversary month of the initial submission, after the initial baseline report is submitted. Report changes to baseline information in the manner described in §803.56 (i.e., include only the new, changed, or corrected information in the appropriate portion(s) of the report form). In each baseline report, you must include the following information:

(1) Name, complete address, and establishment registration number of your reporting site. If your reporting site is not registered under part 807, we will assign a temporary number for use in MDR reporting until you register your reporting site in accordance with part 807. We will inform you of the temporary MDR reporting number;

(2) FDA registration number of each site where you manufacture the device;

(3) Name, complete address, and telephone number of the individual who you have designated as your MDR contact, and the date of the report. For foreign manufacturers, we require a confirmation that the individual submitting the report is the agent of the manufacturer designated under §803.58(a);

(4) Product identification, including device family, brand name, generic name, model number, catalog number, product code, and any other product identification number or designation;

(5) Identification of any device that you previously reported in a baseline report that is substantially similar (e.g., same device with a different model number, or same device except for cosmetic differences in color or shape) to the device being reported. This includes additional identification of the previously reported device by model number, catalog number, or other product identification, and the date of the baseline report for the previously reported device;

(6) Basis for marketing, including your 510(k) premarket notification number or PMA number, if applicable, and whether the device is currently the subject of an approved postmarket study under section 522 of the act;

(7) Date that you initially marketed the device and, if applicable, the date on which you stopped marketing the device;

(8) Shelf life of the device, if applicable, and expected life of the device;

(9) The number of devices manufactured and distributed in the last 12 months and an estimate of the number of devices in current use; and

(10) Brief description of any methods that you used to estimate the number of devices distributed and the number of devices in current use. If this information was provided in a previous baseline report, in lieu of resubmitting the information, it may be referenced by providing the date and product identification for the previous baseline report.

§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?

If you are a manufacturer, when you obtain information required under this part that you did not provide because it was not known or was not available when you submitted the initial report, you must submit the supplemental information to us within 1 month of the day that you receive this information. On a supplemental or followup report, you must:

(a) Indicate on the envelope and in the report that the report being submitted is a supplemental or followup report. If you are using FDA form 3500A, indicate this in Block Item H–2;

(b) Submit the appropriate identification numbers of the report that you are updating with the supplemental information (e.g., your original manufacturer report number and the user facility or importer report number of any report on which your report was based), if applicable; and

(c) Include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s) for reports that cross reference previous reports.

§ 803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with §807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and §807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of

the event to comport with the requirements of § 803.50;

(3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(4) Maintain complaint files in accordance with § 803.18; and

(5) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

Subpart A—General Provisions

Subpart B—Reports and Records

AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

SOURCE: 62 FR 27191, May 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 806.1 Scope.

(a) This part implements the provisions of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and importers to report promptly to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

(b) The following actions are exempt from the reporting requirements of this part:

(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.

(2) Market withdrawals as defined in § 806.2(h).

(3) Routine servicing as defined in § 806.2(k).

(4) Stock recoveries as defined in § 806.2(l).

[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998]

§ 806.2 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Agency* or *FDA* means the Food and Drug Administration.

(c) *Consignee* means any person or firm that has received, purchased, or used a device subject to correction or removal.

(d) *Correction* means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.

(e) *Correction or removal report number* means the number that uniquely identifies each report submitted.

(f) *Importer* means, for the purposes of this part, any person who imports a device into the United States.

(g) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(h) *Market withdrawal* means a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by FDA or that involves